

January 23, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 98N-0313
RIN 0910-AB74
Surgeon's and Patient Exam Gloves Reclassification, proposed rule.

Dear FDA Representative,

I appreciate the opportunity to comment on the FDA's proposed guidelines regarding surgeon's and patient exam gloves. As an anesthesiologist whose career has been destroyed by type I latex allergy, I am eager to see changes that will prevent this from happening to other people.

In general, I applaud the proposed guidelines as a first step toward stemming the current epidemic of latex allergy. I look forward to future steps which will allow individuals, like myself, to return to the healthcare workforce. In reference to the specific areas in which comment was requested:

TIMEFRAME

A one year timeframe should be adequate, since manufacturers have had plenty of warning as to the need to limit powder and protein. I am certain that most are already taking steps to alter their manufacturing procedures. Even the three months added to the comment period will have given them further time to prepare. Knowing what we do now about latex allergy, it is unconscionable to allow more people to become sensitized by waiting any longer than is absolutely necessary.

POWDER LIMIT

Any continued use of powdered gloves is unacceptable. Aeroallergens are an insidious form of exposure. Workers and patients who are not yet sensitized are unaware that they are being bombarded by allergens. Further, aeroallergens make it impossible to provide safe conditions for those already sensitized in any institution where powdered gloves are in use. The notion of "latex-free zones" is laughable where latex laden powder is carried in the air we breathe. Healthcare workers and patients alike deserve protection from this invisible menace.

ADDITIONAL LABELING

Yes, ingredients in glove powdered should be listed on the labels.

POWDER LIMIT ON "POWDER-FREE" GLOVES

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Apparently this is a reasonable limit. Labeling should include amount as well as type of powder.

REQUIREMENT THAT GLOVES BE POWDER-FREE

See comments under "powder limit". I strongly support the notion that all gloves must be powder-free. The benefits of this rule will be tremendous.

LIMIT ON PROTEIN CONTENT

Proposed limits on protein content are based on the current method for measuring protein, specifically the modified Lowry assay. This method has poor sensitivity, and does not specifically measure allergenic proteins. Immunologic assays, such as the ELISA or LEAP, should provide much greater sensitivity, and are specific for allergenic proteins. As soon as possible, these tests should be used instead of the modified Lowry assay. This will allow the FDA to set lower limits on protein, and allow manufacturers to accurately label their products as to protein content. In short, significantly lower protein limits should be set, as soon as the appropriate tests are generally available.

OTHER OPTIONS FOR PROTECTING PUBLIC HEALTH

As stated above, application of enzyme-based assays will allow for accurate detection of lower protein levels. The FDA should also encourage ongoing surveillance of latex allergy.

RECOMMENDED VERSUS REQUIRED LIMITS

Limits on powder and protein must be required. Where there is financial incentive to do otherwise, it is the job of the FDA to protect the public. In the long run, this will benefit manufacturers as well, by "leveling the playing field".

AIR HANDLING SYSTEMS

A ban on the use of powdered gloves will make this unnecessary.

EXEMPTION OR VARIANCE FROM LABELING REQUIREMENTS

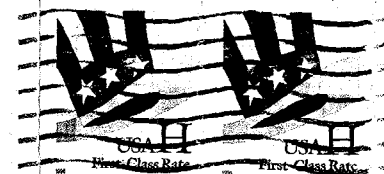
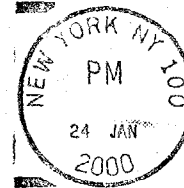
The proposed labeling requirements and standards are good ones. There should be no exemptions.

I look forward to the enactment of the proposed guidelines, as outlined above. They will have a significant positive impact on public health.

Sincerely,

Barbara Zucker-Pinchoff, MD
370 Central Park West #501
New York, NY 10025
Email: BZPMD@aol.com

BARRY S. PINCHOFF
BARBARA ZUCKER-PINCHOFF
370 CENTRAL PARK WEST
NEW YORK, NY 10025-6521



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